FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Psychopharmacologic Drugs Advisory Committee Meeting
The Great Room, White Oak Conference Center, Food and Drug Administration Campus
September 16, 2010

QUESTIONS TO THE COMMITTEE

1. Is the data from the single clinical trial sufficient to conclude that the drug is effective as a treatment for opioid dependence in the patient population that was studied?
   YES/NO/ABSTAIN

2. Can the results observed in the studied population be applied to the US target population?
   YES/NO/ABSTAIN

3. If the answer to question *two* is NO, what additional data are needed (i.e., types of studies)?

4. Taking into account the indication, are the safety data adequate?
   YES/NO/ABSTAIN

5. If the answer to question *four* is NO, what additional safety data are needed to support use of this product?

6. Should this supplement for treatment for opioid dependence be approved?
   YES/NO/ABSTAIN